

# **COLORADO STATE BOARD OF PHARMACY**

**May 14, 2009**

## **Minutes**

The Colorado State Board of Pharmacy meeting was convened by President Paul Limberis, R.Ph., at approximately 8:30 a.m. on Thursday, May 14, 2009 at 1560 Broadway, Conference Room 1380, Denver, CO 80202. Notice of this meeting was given in accordance with Division of Registrations Policy Number 80-17.

Board members attending were: Mary K. Arceneaux, R.Ph., Jeannine G. Dickerhofe, R.Ph., Rich Doyle, R.Ph., Katherine Edelblut, R.Ph., Leonard Hierath, P.E., Paul Limberis, R.Ph., and Averil Strand, R.N.

Staff members attending were Wendy Anderson, R.Ph., Program Director; Chris Gassen, R.Ph., Chief Inspector; and Susan Martin, R.Ph., Inspector. Also present was Jo Kaye, Assistant Attorney General to advise the Board.

### **APPROVAL OF MINUTES**

The Board approved the minutes from the April 23, 2009 meeting and the minutes from the April 30, 2009 meeting.

### **ADDITIONS TO THE AGENDA**

Thomas Fisher, Pharmacy Intern Applicant

### **APPEARANCES**

None

### **HEARINGS**

None

### **REPORTS**

#### **President's Remarks**

Mr. Limbers told the Board that he and Jeannine Dickerhofe would be attending the National Association of Boards of Pharmacy ("NABP") Annual Conference in Miami from May 16 through May 20, 2009. Ms. Dickerhofe will be Colorado's voting delegate. Topics of interest this year include a DEA update, patient counseling, compounding, and technician education.

#### **Program Director's Report**

Ms. Anderson reminded the Board members to let her know if any of them were appointed to a NABP Taskforce. She told the Board members that Ned Calonge, MD, the Chief Medical Director at the Colorado Department of Public Health and Environment would be coming to an upcoming Board meeting to discuss drug distribution and dispensing during emergency medical situations.

The Board considered two applicants for appointment to the Rehabilitation Evaluation Committee ("REC"). After due consideration the Board appointed Randy Knutsen, RPH, to the REC.

The Board then considered a report from Ms. Anderson and another from Inspector Mark O'Neill discussing training programs for immunization administration. In addition, the Board considered revisions to Rule 19.00.00 proposing changes to the requirements for immunization administrations. After due consideration, the Board moved the proposed changes to hearing.

The Board then considered a report from Ms. Anderson detailing a non-licensed pharmacy intern practicing in the State of Colorado. After due consideration, the Board voted to deny the intern hours for this individual and to issue complaints against Bradley Stoltz, RPH 16105, and Cardinal Pharmacy, PDO 149.

The Board then reviewed the NABP "Report of the Task Force to Review Accreditation Standards for Community Pharmacy." The Board noted that Mr. Limberis had served on the Taskforce.

#### **Colorado Pharmacists Society (CPS) – Rich Doyle, RPh**

The next Continuing Education ("CE") program is the Annual Summer Meeting to be held June 26-28, 2009 in Copper Mountain, Colorado. Eleven hours of CE will be offered. The education programs will include a new drug update, programs that focus on quality assurance, improved disease state management skills, as well as helping to maintain continuing competency in drug therapy and pharmacy law. The business session will include the State of the Society Report. The awards and installation dinner will recognize the Bowl of Hygeia winner, Larry Clark and the incoming president, Carole Shelton, will present her inaugural address. Details are on the CPS website, [www.copharm.org](http://www.copharm.org).

The next major CE event will be 2009 CPS Annual Fall Meeting to be held September 24-26, 2009 at the Stapleton Radisson in Denver. This year the meeting will be held in conjunction with the Colorado Society of Parenteral and Enteral Nutrition. The Friday program on September 25<sup>th</sup> will provide education programs for health-system pharmacists. The Saturday program will be for community/retail pharmacists. Fifteen hours of ACPE approved continuing education will be provided and details will be posted on the CPS website.

Planning has begun for the 2010 Winter CE Seminar to be held January 10-13, 2010 in the Avon Westin. Fifteen hours of CE programming will be offered and details will be on the CPS website.

#### **Governor's Expert Emergency Epidemic Response Committee (GEEERC) – Paul Limberis, RPh**

The GEEERC had a number of telephone conferences with the members along with other individuals over the course of April 24 through April 28, 2009 concerning the outbreak of Swine Flu in the United States. Colorado received a portion of the Strategic National Stockpile of Tamiflu and Relenza. There are enough doses to take care of approximately 167,000 courses of therapy. The distribution system has been put into place and sites are

able to obtain a portion or all of their allotment of Relenza and Tamiflu.. As of May 13, 2009 there are 52 cases of H1N1 in Colorado. Ages of patients are <5 years through the 40-59 year old age category. The majority are in the 18-39 year old category. Five hospitalizations were reported as of May 12, 2009. The next GEEERC meeting is scheduled for July 2, 2009.

### **Intern & School Relations – Jeannine Dickerhofe, RPh**

Lane Brunner, the Dean of Regis University School of Pharmacy reported on the school's site visit from the American Council of Pharmacy Education ("ACPE"). He reported that the visit went very well. He stated that the school received 747 applications for 50 openings for the fall 2009 class. The school will find out in June 2009 if it has received Pre-Candidate status from ACPE.

Cathy Jarvis from the University of Colorado School of Pharmacy reported that the school will graduate 120 students this spring. She updated the Board on the school's budget issues.

### **Legislation - Jeannine Dickerhofe, RPh.**

The proposed reduction for pharmacy reimbursement for Medicaid prescriptions from the current AWP-13.5% to AWP- 14.5% for brand and the current AWP-35% to AWP-45% for generics was scheduled to go into effect on July 1, 2009. The Joint Budget Committee (JBC) was considering delaying this reduction to April 2010. The latest recommendation by the JBC is to have January 1, 2010 as the implementation date. Colorado pharmacy organizations have requested that the Department of Health Care Policy and Financing (Medicaid) consider an earlier implementation date but at a lower rate reduction. The analyst for HCPF will provide a report to the JBC within the next month of what the lower rate reduction should be in order to achieve the same amount of savings.

The FDA is announcing a public meeting to obtain input on developing Risk Evaluation and Mitigation Strategies (REMS) for certain opioid drugs. The REMS would be intended to ensure that the benefits of these drugs continue to out weigh certain risks. The agency has long been concerned about adverse events associated with this class of drug and has taken steps in cooperation with drug manufacturers to address these risks. They intend to use the agency's REMS authority under the Food and Drug Administration Amendments Act of 2007 (FDAAA) to mitigate the risks of these drugs.

The affected opioid drugs include brand name and generic products that are formulated with the following active ingredients: fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone.

The elements to assure safe use must include one or more goals to mitigate a specific serious risk listed in the labeling of the drug. These elements may include the following requirements:

- Pharmacies, practitioners, or healthcare settings that dispense the drug are specially certified.
- The drug is dispensed to patients only in certain health care settings.
- The drug is dispensed to patients with evidence of safe use conditions, such as laboratory test results.

- Each patient using the drug is subject to certain monitoring.
- Each patient using the drug is enrolled in a registry.
- The elements to assure safe use may also include an implementation plan, whereby the applicant monitors, evaluates, and works to improve the implementation of certain of these elements.

To see the complete notice and additional proposals, go to the link <http://edocket.access.gpo.gov/2009/pdf/E9-8992.pdf>. To submit comments electronically go to <http://www.regulations.gov>. **[Docket No. FDA-2009-N-0143]**

### **Rules – Rich Doyle**

None.

### **Inspectors**

None.

## **OLD BUSINESS**

### **Stipulations**

#### **Diffendaffer, Rodney J., RPH 14639**

The Board reviewed an Agenda Memorandum from Tia Johnson, Complaint/Licensing Analyst, concerning Mr. Diffendaffer's request for discharge from the terms of his Stipulation and Final Agency Order. After due consideration of the available information, the Board released Mr. Diffendaffer from his stipulation.

#### **Fossenier, Thomas S., RPH 12588**

Paul Limberis recused.

The Board reviewed an Agenda Memorandum from Ms. Johnson concerning Mr. Fossenier's request for discharge from the terms of his Stipulation and Final Agency Order. After due consideration of the available information, the Board released Mr. Fossenier from his stipulation.

#### **Gerken, Gale L., RPH 11135**

The Board reviewed an Agenda Memorandum from Ms. Johnson concerning Ms. Gerken's request for discharge from the terms of her Stipulation and Final Agency Order. After due consideration of the available information, the Board released Ms. Gerken from her stipulation.

#### **Jones, Tony E., RPH 14967**

The Board reviewed an Agenda Memorandum from Ms. Johnson concerning Mr. Jones' request for discharge from the terms of his Stipulation and Final Agency Order. After due consideration of the available information, the Board released Mr. Jones from his stipulation.

#### **Lapp, Robert E., RPH 11555**

The Board reviewed an Agenda Memorandum from Ms. Johnson concerning Mr. Lapp's request for modifications to his stipulation and final agency order. After due consideration, the Board denied the request.

**Star Drug, PDP 125-3**

The Board reviewed an Agenda Memorandum from Ms. Johnson concerning Star Drug's request for discharge from the terms of its Stipulation and Final Agency Order. After due consideration of the available information, the Board released Star Drug from its stipulation.

**MISCELLANEOUS**

**Peak Vista Family Health Center at Myron Stratton**

The Board considered a request from Paul Reilly, RPH, for the Board to clarify exactly what the facility could do to reduce the visitation schedule for its consultant pharmacist. After due consideration, the Board declined to offer suggestions for the facility. It suggested that the facility could either reduce the number of prescriptions dispensed or review rule 14.00.60 and implement additional technology which helps to ensure safe dispensing.

**Referral from the Colorado Board of Medical Examiners**

The Board reviewed additional information from Inspector Mark O'Neill. After due consideration, it voted to initiate complaints against the following:

Stephen Bergan, RPH 10024  
Pamela Weber, RPH 17048  
Vincent Skorey, RPH 17189  
Walgreen Pharmacy #5645, PDO 82-2.

**Complaints**

**Berhe, Mulugeta W., RPH 18256**

**2009-3257**

A motion was made, seconded, and carried to dismiss the case as being without merit.

**Henderson, Margaret D., RPH 16803**

**2009-3150**

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

**Ornes, Beverly, RPH 12044**

**2009-2224**

The Board voted to table action on this matter.

**Tri-County Health Department**

**2009-2982**

After due consideration of the available information, the Board voted to refer the case for discipline.

**LICENSING**

**Other Outlets, New**

The Board approved the registration of 0 new other outlets.

**Prescription Drug Outlets, New (In-State)**

The Board approved the registrations of 2 new in-state prescription drug outlets.

**Prescription Drug Outlets, New (Out-of-State)**

The Board approved the registrations of 5 new nonresident prescription drug outlets.

**Manufacturers, New**

The Board approved the registrations of 0 new manufacturers.

**Limited Licenses, New**

The Board approved the registrations of 0 new limited licenses.

**Wholesalers, New (In-State)**

The Board approved the registrations of 0 new in-state Wholesalers.

**Wholesalers, New (Out-of-State)**

The Board approved the registrations of 35 new out-of-state Wholesalers.

**Licensure by Examination and Score Transfer**

The Board ratified the licensure of 1 applicant for licensure.

**Licensure by License Transfer**

The Board ratified the licensure of 6 applicants seeking licensure through license transfer. It was noted that these licensees met all of the requirements for licensing under the provisions of section 12-22-116, C.R.S.

**LICENSURE ISSUES**

**Arrow International, Out-of-State Wholesaler Applicant**

After review of the available information, the Board voted to approve the registration.

**Paddock Laboratories, Out-of-State Wholesaler Applicant**

After review of the available information, the Board voted to approve the registration.

**Thomas Fisher, Pharmacy Intern Applicant**

After review of the available information, the Board voted to table action pending an evaluation of the applicant.

**MISCELLANEOUS**

**Correspondence, etc.**

**National Association of Boards of Pharmacy ("NABP") Report of the Task Force to Review TOEFL iBT Score Requirements.**

The Board noted the information.

**Information from NABP regarding Drug Enforcement Administration Interpretation of Emergency Schedule II Refills**

The Board noted the information.

**NABP Report of the Task Force on Uniform Prescription Labeling Requirements**

The Board noted the information.

**Peer Assistance Services—Third Quarter Report**

The Board noted the information.

**EXECUTIVE SESSION**

Board President Paul Limberis moved that the Board enter into executive session as authorized by CRS 24-6-402 subsection (3)(a) roman (III) to discuss matters which are required by law to be kept confidential. Specifically, the provisions of law requiring these matters to be kept confidential are:

CRS 24-6-402 subsection (3)(a) romans (II) and (III), and section 13-90-107(b), which protect as confidential communications with counsel that are matters of pending or imminent litigation, or are otherwise subject to the attorney-client privilege, and CRS 25-1-1201 et sequitor, which protects the confidentiality of information pertaining to individual medical records.

The motion was unanimous.

The Board discussed the case status report from the Office of Expedited Settlement.

The Board discussed all items referred to it earlier in the meeting as well as matters confidential by law.

**Open Session**

**2009-3227**

A motion was made, seconded, and carried to dismiss the case as being without merit.

**2009-2937**

After due consideration, the Board tabled action on this matter.

**2009-2938**

A motion was made, seconded, and carried to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

The Board voted to accept PR-09-162 and PR09-163 into the Pharmacy Peer Health Assistance Diversion Program.

The Board voted to notify Pharmacy Peer Health Assistance Diversion Program participant PR-07-128 to comply with the Peer Assistance Services Contract within fourteen days or face suspension of his/her pharmacist license.

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The Board voted to notify Pharmacy Peer Health Assistance Diversion Program applicant PR09-160 to sign his/her contract with Peer Assistance Services within fourteen days or face suspension of his/her pharmacist license.

**2009-0057**

The Board voted to rescind the referral of this matter to the Office of the Attorney General and dismiss the case.

**ADJOURNMENT**

The Board adjourned at approximately 4:00 p.m.

*Approved by Paul Limberis, R.Ph., President      Date: July 16, 2009*